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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,349

06/23/2006

Heinrich Haas

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,349	Applicant(s) HAAS ET AL.	
	Examiner Gollamudi S. Kishore	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6-23-06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 1-12 and 14.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'a pH active agent' in (e) of claim 1. Does the term mean a buffer or an acid or a base to bring the composition to an appropriate pH? Furthermore, according to (e) the concentration of this agent is from 0 mM to about 10 mM; claim 1 also requires the pH of the composition to be 5 to 9. If an acid or a base constitutes the pH active agent and if it is at 0 mM concentration, then how can the pH be either acidic or alkaline? It will be neutral since no buffer or an acid or a base is present.

The term, 'preferably' renders claims 5, 6, 8, 9, 10 indefinite since it is unclear whether the limitation following this term is indeed the limitation. Similar is the case with the term, 'more preferably'.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez-Soler (5,834,012) of record in view of Janoff (5,578,320).

Perez-Soler discloses cationic liposomes containing camptothecins. The camptothecins can be in lactone form or in a carboxy form. The cationic lipids include DOTAP. The liposomes further contain an amphiphile, DOPC in an amount of 40 % and cholesterol (abstract, col. 3, lines 20 through col. 4, line 67; examples and claims). The ratio of the lipid to drug is 5:1 to 100:1 (claims). The buffer used is phosphate buffer (Example 1).

What is lacking in Perez-Soler is the dehydration of the liposomes and subsequent rehydration in the presence of cryoprotectants.

Janoff teaches that liposomes can be dehydrated in the presence of a cryoprotectant both inside and outside and stored for extended periods of time without substantial leakage from the liposomes of internally encapsulated materials and rehydrated again with an aqueous medium (abstract, col. 1, line 62 through col. 2, line 59; examples and claims).

To subject the cationic liposomes containing camptothecin carboxylate to dehydration-rehydration procedure in the presence of cryoprotectants taught by Janoff would have been obvious to one of ordinary skill in the art since one can store the dehydrated liposomes for a long time. Camptothecin is a known anti-cancer agent and therefore, the use of the composition for the treatment of angiogenesis involving diseases such as cancer would have been obvious to one of ordinary skill in the art with

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a reasonable expectation of success. The references of Perez-Soler and Janoff do not teach the inclusion of anti-oxidant. Such an inclusion however, would have been obvious to one of ordinary skill in the art since such an inclusion is art known.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez-Soler (5,834,012) in view of Janoff (5,578,320) as set forth above, further in view of Yamauchi (US 2002/0182248).

As pointed out above, the references do not teach the inclusion of an antioxidant.

The references of Yamauchi shows that anti-oxidants such as vitamin C and vitamin E are stabilizing agents for liposomes containing active agents such as camptothecin (0031, 0042, 0048 and 0051).

The inclusion of antioxidants in the compositions of Perez-Soler and Janoff would have been obvious to one of ordinary skill in the art since they are stabilizing agents in liposomal formulations as shown by Yamauchi.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez-Soler (5,834,012) in view of Janoff (5,578,320) as set forth above, further in view of Jackson (US 2004/0220131).

What is lacking in Perez-Soler and Janoff is the use of the compositions for the treatment of angiogenic diseases.

Such a use however, would have been obvious to one of ordinary skill in the art since Jackson teaches that camptothecin containing compositions can be used to inhibit angiogenesis (0024).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-72 of copending Application No. 11/018574. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to a method of preparation of the liposomes. Claims in the copending application are generic with respect to the active agent and therefore, instant species is anticipated. Claims in said copending application recite an additional step of preparing the liposomes before dehydration and instant claims do not exclude such a step since solvent evaporation and hydration are the routine method of preparation steps practiced in the art.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK